

spondylitis (AS). **METHODS:** Infliximab and etanercept significantly improve signs and symptoms of AS. We analyzed their cost-efficacy based on incremental benefit versus placebo in their respective AS pivotal trials. Inclusion and exclusion criteria were similar for both trials except for permitted concomitant medications. The base model estimates cost efficacy for maintenance therapy, compared to placebo. Costs were estimated based on average dose for a patient receiving maintenance therapy over a 1-year period. The average number of infliximab vials per dose (4) and total doses/year per patient (8) were obtained from ASSERT trial data. Etanercept was assumed to be administered at 25 mg/dose twice weekly. The ASAS 20, ASAS partial remission, DCART 20 response rates, and percent improvement in BASFI at week 24 were used as efficacy measures. **RESULTS:** In the infliximab trial, 201 patients received infliximab (5 mg/kg) and 78 patients received placebo. In the etanercept trial, 138 patients were treated with etanercept 25 mg twice weekly and 139 received placebo. The cost per responder for infliximab as measured by ASAS 20, ASAS partial response, and DCART 20 was \$44,790, \$89,156, and \$54,057, respectively. The corresponding costs per responder for etanercept were \$43,271, \$116,500, and \$58,250. The mean percent improvement in BASFI in the infliximab and placebo arms were 38.5% and 0.1% respectively, leading to a cost per percent BASFI improvement of \$490. The corresponding numbers for etanercept were 30% and 2%, leading to a cost per percent BASFI improvement of \$541. **CONCLUSIONS:** The cost-efficacy ratios of infliximab and etanercept maintenance therapies compared to placebo were similar. The cost-effectiveness in clinical practice will depend on the actual dose and effectiveness achieved. Incremental cost-effective comparisons cannot be reliably estimated without a head-to-head trial.

PAR12

HOW ADEQUATE DO RA-PATIENTS REPORT INDIRECT COSTS?—THE EXAMPLE OF A GERMAN COHORT

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OBJECTIVES: To render information on the accuracy of patient-reported indirect cost data. By comparing questionnaire-derived data to payer-derived data on a patient-by-patient basis disease related productivity losses in rheumatoid arthritis (RA) are being validated. **METHODS:** The assessment of indirect cost data was part of a clinical multicenter randomized RA-trial in Germany. For 234 RA-patients at working age (1987 ACR criteria, membership in the regional statutory health insurance plan, mean age 53 (±9) years, mean disease duration 8 (±7) years, 76% females) every three months corresponding indirect cost data were derived from (i) a health economic questionnaire for cost assessment in patients with RA and (ii) the payer's database (insurance and physicians' association) over a period of 18 months. Comparative statistical analyses were performed between patient reported and insurance claims data. **RESULTS:** The mean annual productivity losses due to sick leave amounted to 14 and 17 days per patient (questionnaire versus payer data), productivity losses due to work disability to 3 days (both); monetary valuation renders overall costs of 1240€ and 1590€, respectively. The difference of 17% in overall productivity losses is not significant. Comparison of productivity losses reveals a strong correlation of $r = 0.83$ in those due to sick leave and of $kappa = 0.84$ in those due to work disability between questionnaire and payer data. **CONCLUSIONS:** The comparison of questionnaire and payer data shows that RA-patients report their productivity losses adequately. Indirect cost assessment should therefore be included in

further RA-trials and observational studies, even if payer-derived data is not available.

PAR13

COST-EFFECTIVENESS OF VALDECOSIB COMPARED TO DICLOFENAC IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) IN THE UK (UK) AND GERMANY

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OBJECTIVE: To compare the cost-effectiveness of valdecoxib 20 mg once daily (qd) and diclofenac 75 mg slow release (SR) twice daily (bid) in the treatment of RA based on prospectively collected data of Health Care resource utilization in a randomized controlled trial (RCT, study 062) over 6 months. The cost-effectiveness evaluations were calculated for the UK from a National Health Service payer perspective, and for Germany from a Sickness funds payer perspective. **METHODS:** Study 062 compared efficacy and safety of valdecoxib 20 mg qd ($n = 246$) with diclofenac 75 mg SR bid ($n = 237$) in adult patients with RA. The cost-effectiveness of valdecoxib and diclofenac was compared using country-specific unit costs for resource use (hospital days, medications, unscheduled procedures and health care visits) in the UK and Germany. The cost-effectiveness ratios were calculated for cost/averted gastroduodenal (GD) ulcer, cost/averted withdrawal due to treatment failure and/or adverse event, cost/averted gastrointestinal (GI) serious adverse event (SAE), and cost/avoided ulcer with GI SAE. **RESULTS:** The study showed comparable efficacy and a superior safety profile for valdecoxib, resulting in fewer GI adverse events and hospital days. The cost/averted GD ulcer in the UK was -£1104 and 386€ in Germany. The cost/averted withdrawal due to treatment failure and/or adverse event was -£1580 in the UK and 553€ in Germany. The cost/averted GI SAE was -£2709 in the UK and 947€ in Germany, and the cost/avoided ulcer with GI SAE was -£3522 in the UK and 1436€ in Germany. **CONCLUSIONS:** The superior safety profile of valdecoxib compared with diclofenac translates into lower total health care costs for patients treated with valdecoxib, and overall cost effectiveness in both countries.

PAR14

COSTS OF RA IN GERMANY ON A MICRO-COSTING LEVEL

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OBJECTIVES: To develop a systematic set of German cost data in RA based solely on valid health care payer's cost data sources on a patient—per—patient micro-costing level. **METHODS:** Retrospectively one-year cost data of 338 RA patients were generated and analyzed. The cost data were derived from a major statutory health insurance plan ("Allgemeine Ortskrankenkasse Niedersachsen") and the regional physicians' association ("Kassenärztliche Vereinigung Niedersachsen"). A matrix of cost domains in RA was applied to structure the analysis. Descriptive statistics were used to analyze the data. **RESULTS:** The total direct costs for the 338 patients during the one year period (3rd quarter 2000—2nd quarter 2001) were 3815€ per patient-year. RA-related direct costs were 2312€ per patient-year. Outpatient costs accounted for 73.7%, inpatient costs for 24.0%, and other disease-related costs for 2.3% of RA-related direct costs. Outpatients costs drivers were: RA-related medication (1019€ per patient-year), physician visits (323€ per patient-year), diagnostic and therapeutic procedures and tests (185€ per patient-year), and devices and aids (168€ per patient-year). Ninety-eight patients

were retired prematurely due to RA-related work disability and incurred costs of 8358€ per retired patient-year. Ninety-six patients were gainfully employed and incurred sick leave costs of 2835€ per employed patient-year. **CONCLUSIONS:** Micro-costing based on health care payer's data provides a relatively conservative albeit highly accurate estimate of costs in RA. It is important to take both RA-related and non-RA-related costs into account. Medication costs are the dominant direct component with an increase due to the introduction of biologic agents. In gainfully employed patients and in patients who receive RA-related retirement payments productivity costs exceed direct costs.

PAR15

A COMPARISON OF COST OF INFLIXIMAB AND ETANERCEPT IN THE TREATMENT OF RHEUMATOID ARTHRITIS IN ITALY: RESULTS OF THE IERI STUDY GROUP De Portu S¹, Ferraccioli G², Sarzi-Purrini P³, Fiocco U⁴, Montecucco C⁵, Valesini A⁶, Canesi B⁷, Leardini G⁸, Mecchia M⁹, Mantovani LG¹

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OBJECTIVE: Rheumatoid Arthritis (RA) is a disease with high socioeconomic impact. Anti-TNF drugs have provided evidence of effectiveness in treating RA patients resistant to 2 previous conventional DMARDs, including MTX, as demonstrated by a number-needed-to-treat (NNT) of 2 to produce a 20% improvement in American College of Rheumatology (ACR) score (ACR20). Anti-TNF therapy is also costly. The aim of this retrospective longitudinal cost of care analysis was to evaluate the cost of Etanercept (ETA) vs Infliximab (IFX) used at the standard dosage (according to the ANTARES Protocol) for the treatment of RA patients after DMARDs (disease-modifying anti-rheumatic drugs) failure in Italy. **METHODS:** The study included subjects randomly enrolled from 7 centres participating to a prospective data collection program called ANTARES. Direct health care resources attributable to RA management (drugs, ambulatory care, day case treatments, hospitalizations) were quantified using National Health Service (NHS) tariffs expressed in Euro 2003. NHS perspective was adopted. Multiple linear regression techniques were used to investigate differences between IFX and ETA in the direct cost, adjusting for sex, age, baseline ESR (erythrocyte sedimentation rate), baseline DAS (disease activity score) and centre. **RESULTS:** A total of 211 (IFX 101, ETA 110) patients affected by RA (F/M 165/46; mean age 50.7 ± 14.5 years old) were studied. Mean total annual direct costs for RA patients were euro 16,988 (±7245). The regression analysis showed that adjusting for sex, baseline ESR, age, baseline DAS and centres total direct costs per patient in ETA group were 3427 Euro lower than in IFX patients ($P < 0.0001$). **CONCLUSIONS:** The total direct cost of Etanercept is statistically significantly lower than Infliximab, when the drug are used at the standard dosage, according to the ANTARES Protocol.

PAR16

CO-PAYMENTS IN RHEUMATOID ARTHRITIS OBSERVED IN A GERMAN COHORT

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OBJECTIVES: The aim was to focus on the financial burden of co-payments for patients with rheumatoid arthritis under new German law regulations. **METHODS:** The assessment of all cost data was part of a clinical multicenter randomized RA-trial in Germany. For 136 RA-patients (1987 ACR criteria, mean age 57.4 (±12.5) years, mean disease duration 8.2 (±8.4) years, 77% females) every 3 months corresponding cost data were derived from 1) a RA-related patient-centered health economic questionnaire, and 2) the payer's database (insurance and physicians' association) over a period of 18 months. Co-payments in Germany partly can be derived by analyzing the payers' data due to specific legal regulations. In addition to that patient-derived data was evaluated. **RESULTS:** The data was composed in a matrix of different cost domains. Those led to patient co-payments/ year of 417.10€. Visits to a physician accounted for 9.2% (38.40€), non-physician service utilization for 46.6% (194.40€), medication for 23.7% (99€), hospital co-payments for 5.8% (24€), transportation for 13.5% (56.20€), and devices and aids for 1.2% (5.10€) of the overall co-payment costs. **CONCLUSIONS:** The impact of co-payments on patients with chronic diseases needs to be addressed by policy makers. Even in an environment with relatively low co-payment regulations like Germany the burden for RA-patients can become substantial.

ARTHRITIS

ARTHRITIS—Quality of Life/Utility/Preference Studies

PAR17

LINGUISTIC ADAPTATION AND VALIDATION OF THE ARTHRITIS TREATMENT SATISFACTION QUESTIONNAIRE (ARTS) INTO SPANISH

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OBJECTIVES: ARTS is a self reported instrument designed to measure four treatment satisfaction dimensions: Treatment advantages, Treatment convenience, Apprehension about treatment and Satisfaction with medical care; and is composed by 18 Likert-scale items. It is intended to be used with patients suffering osteoarthritis and undergoing oral administered treatments. **METHODS:** Linguistic adaptation was performed using the standard processes for establishing conceptual equivalence. A panel of six experts supervised the process and four independent translators translated and back-translated the items. A sample of 163 patients was used to gauge psychometric properties. All patients suffered from knee, hip or column arthritis. Patients were included in 3 groups: treatment-switch because of a weak analgesic effect, treatment-switch due to poor tolerability and no-change. The ARTS was administered at baseline, 1 week later and after 4 weeks of therapy with traditional NSAIDs or Cox II-inhibitors. **RESULTS:** Mean age was 67.7 ± 9.2 years old. The adapted instrument showed good feasibility and reliability properties. No floor or ceiling effects were found, items were well understood and non-response rates were below one percent (1%). Cronbach's alpha for the total scales was 0.85. Instrument was stable with a test-retest intraclass correlation coefficient of 0.83. Exploratory factor analysis yielded four dimensions coherent with those proposed by the original authors. Convergent validity was measured against SF-36, a pain VAS a treatment compliance VAS, and Morisky-Green compliance questionnaire. The adapted instrument showed good discriminant validity, being able to distinguish between patients needing a change in